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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GREGORY ALAN LAZAR, ARTHUR J. CHIRINO, WEI DANG,
JOHN RUDOLPH DESJARLAIS, STEPHEN KOHL DOBERSTEIN,
ROBERT J. HAYES, SHER BAHADUR KARKI, and OMID VAFA

Appeal 2010-012556
Application 10/672,280
Technology Center 1600

Before ERIC GRIMES, LORA M. GREEN and STEPHEN WALSH,
Administrative Patent Judges.

GREEN, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

Appellants request reconsideration of the Decision on Appeal entered March 17, 2011 (“Decision”), which affirmed the rejection of all pending claims for obviousness. We have considered the arguments presented, but deny the requested relief.

BACKGROUND

The claims are drawn to an antibody or immunoadhesin having defined amino acid substitutions. The claims on appeal were rejected for obviousness, and this panel affirmed. Appellants request rehearing, alleging these errors:

- I. The Board overlooked the fact that it had previously held that Presta did not teach particular individual substitutions at stated positions.
- II. The Board overlooked the teachings of the reference as a whole.
- III. The Board overlooked the selection of a lead compound.
- IV. The Board overlooked that obviousness cannot be predicated on the unknown.
- V. The Board overlooked the lack of predictability of amino acid substitutions based on activity.

ANALYSIS

- I. The Board overlooked the fact that it had previously held that Presta did not teach particular individual substitutions at stated positions

Appellants assert that the Panel erred in not finding *Ex parte Watkins* (Appeal 2007-2523, decided September 12, 2007) controlling in the instant appeal, arguing that Presta served as prior art in that case as well as the instant Appeal, and that both positions 239 and 280 are recited in claim 13 of Presta (Req. Reh'g 4). Specifically, Appellants assert that in *Watkins* the panel noted “that ‘we do not agree that Presta provides a specific teaching of substituting the amino acid at position 280 with each of these twenty amino acids’” (*id.* at 5 (quoting *Watkins, slip opinion* at 6)).

As we noted in the Decision (Decision, p. 7), *Watkins* is not precedential, involved a different residue (280), as well as a different rejection (the rejection was under § 102(e)). The panel in that decision made no findings or conclusions as to the obviousness of substitutions at different positions, and we decline to read that decision as doing so.

II. The Board overlooked the teachings of the reference as a whole.

Appellants argue that the Decision misapprehended the term “amino acid” as used in Presta, and overlooked the total teachings of claim 13 of Presta, which recites 59 different positions (Req. Reh’g. 5-6). Appellants assert to select position 239 from that list is impermissible hindsight (*id.*).

Appellants assert further that in finding that it would have been obvious to substitute the amino acid at position 239 with another amino acid, that the panel overlooked 5 references in Presta associating position 239 with reduced binding activity (Req. Reh’g 6). Appellants assert further that the subject matter of claim 13 “should be weighted, given its reliance on post-filing amendments” (*id.* at 7).

We point Appellants’ attention to FF4-FF11 of the Decision (Decision, pp. 4-5). Thus, the panel did not only rely on claim 13 of Presta in finding the claimed antibody obvious, but on the teachings of the Presta reference as a whole (*see, e.g. id.* at 8-9).

Moreover, we reiterate that Presta teaches that certain variants may have decreased binding to one FcγR, but increased binding to another (*id.* at 4, FF7). Thus, Presta contemplates variants that both increased and decreased binding affinity. Presta also teaches conservative substitutions,

such as T for S (*id.* at FF9). Thus, as Presta specifically teaches that the serine at position 239 may be substituted, and specifically teaches the S to T conservative substitution, we conclude that the S239T antibody or immunoadhesin variant is rendered obvious by Presta (*id.* at 8-9).

III. The Board overlooked the selection of a lead compound.

Appellants argue that “Presta does not provide any reason for selecting 239DEQT” (Req. Reh’g 8). Appellants further assert that a “conservative substitution of wt residue Ser would at best be expected to give wild-type activity and, thus, no increased activity” (*id.* at 9). Appellants assert further that the Board ignored the relevance of *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), and that structural similarity alone is not sufficient to establish obviousness, there must have been some reason to modify the compound with a reasonable expectation that the new compound would have the same or improved properties (Req. Reh’g 8-9).

The panel distinguished the instant appeal from *Takeda* (Decision, p. 9). Moreover, as discussed, Presta specifically teaches a substitution at serine 239, and teaches that conservative substitutions may be made. Thus, at the very least, the ordinary artisan would expect an antibody with similar binding properties to the wild type antibody.

IV. The Board overlooked that obviousness cannot be predicated on the unknown.

Appellants argue in response to the panel's statement that an S239T variant would inherently have the property of increased binding to FcγR, that there can be no inherency as Presta does not specifically teach that variant (Req. Reh'g 11).

The panel's point was that the claims are drawn to a compound, that is, to an antibody or an immunoadhesin (Decision, p. 8). As discussed above, Presta, at a minimum, renders obvious the S239T variant (*id.*). As a compound cannot be separated from its properties, such a variant would inherently have the increased binding to FcγR (*id.*).

V. The Board overlooked the lack of predictability of amino acid substitutions based on activity

Appellants argue that the Board overlooked the data in Presta demonstrating significant variation in activity associated with different amino acid substitutions, demonstrating the unpredictability of substituting different amino acids (Req. Reh'g 12). Appellants assert that such unpredictability "supports a finding of unexpectedness and thus non-obviousness" (*id.*).

Appellants' arguments are not convincing, as Presta recognizes that a substitution may result in different binding affinities, and teaches methods of assaying for the same (*id.* at 4, FF7, *see also id.* at 10). As set forth above, Presta renders obvious the S239T variant, and thus renders obvious the claims on appeal.

CONCLUSIONS

We have considered Appellants' request, but find the evidence supports the findings of fact in the original Decision.

SUMMARY

We deny the requested relief.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

DENIED

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